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EXAMINER

NAJARIAN, LENA

ART UNIT

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1 UNITED STATES PATENT AND TRADEMARK OFFICE

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4 BEFORE THE BOARD OF PATENT APPEALS
5 AND INTERFERENCES
6

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8 *Ex parte* FRANK R. RUDERMAN and DAVID T. SHEWMAKE
9

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11 Appeal 2008-1943
12 Application 09/534,946
13 Technology Center 3600
14

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16 Decided: January 30, 2009
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19 *Before* MURRIEL E. CRAWFORD, DAVID B. WALKER, and JOSEPH A.
20 FISCETTI, *Administrative Patent Judges*.

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22 CRAWFORD, *Administrative Patent Judge*.
23

24
25 DECISION ON APPEAL
26

27 STATEMENT OF THE CASE

28 Appellants appeal under 35 U.S.C. § 134 (2002) from a Final
29 Rejection of claims 22 to 28 and 38. We have jurisdiction under 35 U.S.C.
30 § 6(b) (2002).

1 Appellants invented a cardiovascular healthcare management system
2 that identifies patients who do not have hyperlipidemia based on total LDL
3 cholesterol and total HDL cholesterol, but are in need of treatment. The
4 cardiovascular healthcare management system includes a diagnostic engine
5 which analyzes patient test results for subclasses of LDL and HDL including
6 HDL 2b (Specification 1, 14 to 15).

7 Claim 38 under appeal reads as follows:

8 38. A cardiovascular healthcare
9 management system comprising:

10 (a) an infomediary site having databases for
11 cardiovascular healthcare management which
12 includes a database of test results of concentration
13 of subclasses of LDL particles and subclasses of
14 HDL particles from at least 900 cardiovascular
15 patients;

16 (b) a data entry interface for receiving
17 patient personal data and test results for
18 concentration of subclasses of LDL particles and
19 subclasses of HDL particles storing the data and
20 results in the infomediary site databases;

21 (c) a diagnostic engine for analyzing patient
22 test results for subclasses of LDL particles,
23 subclasses of HDL particles data and identifying
24 patients who do not have hyperlipidemia based on
25 total LDL cholesterol and total HDL cholesterol,
26 but are in need of treatment; and

27 (d) wherein the subclasses of LDL particles
28 and subclasses of HDL particles are levels
29 determined by segmented gradient gel
30 electrophoresis and wherein the particle sub-classes
31 include HDL 2b.
32

1 The Examiner rejected claims 22, 24 to 28 and 38 under 35 U.S.C. §
2 103(a) as being unpatentable over Levin in view of Otvos, Krauss, and
3 Appellants' Admitted Prior Art ("AAPA").

4 The Examiner rejected claim 23 under 35 U.S.C. § 103(a) as being
5 unpatentable over Levin, Otvos, Krauss, AAPA and Surwit.

6 The prior art relied upon by the Examiner in rejecting the claims on
7 appeal is:

8	Levin	US 5,724,580	Mar. 3, 1988
9	Krauss	US 5,925,229	Jul. 20, 1999
10	Surwit	US 6,024,699	Feb. 15, 2000
11	Otvos	US 6,576,471 B2	Jun. 10, 2003

12
13 Appellants' Admitted Prior Art ("AAPA") on page 1 of the Specification.

14
15 Appellants contend that the cited prior art does not include a
16 diagnostic engine which analyzes test results for patients of levels of LDL
17 and HDL subclasses for identifying patients who do not have hyperlipidemia
18 based on total LDL cholesterol and total HDL cholesterol, but are in need of
19 treatment and wherein the particle subclasses include HDL 2b.

20 21 ISSUES

22 Have Appellants shown that the Examiner erred in holding that the
23 prior art discloses a diagnostic engine, which analyzes test results for
24 patients of levels of LDL and HDL subclasses for identifying patients who
25 do not have hyperlipidemia based on total LDL cholesterol and total HDL
26 cholesterol but are in need of treatment and wherein the particle subclasses
27 include HDL 2b.

FINDINGS OF FACT

FF1. Appellants disclose at page 1 of the Specification that:

The art describes cardiovascular risk factors such as age, smoking, weight, family history, blood pressure, lipid profiles including low density lipoprotein (LDL) and high density lipoprotein (HDL) and subclasses (fractions) of LDL and HDL. Methods for measuring these factors and relating them to patient treatment are also known.

FF2. Levin discloses a system for managing coronary disease having databases for cardiovascular healthcare management which includes database test results including LDL and HDL concentrations to calculate total cholesterol (Figure 4, col. 8, ll. 21 to 47).

FF3. Otvos discloses that commercially prepared lipid panels only include total cholesterol, total HDL and total LDL rather than LDL and HDL subclass information. (Col. 1, ll. 43 to 48). Otvos discloses that NMR analysis provides information about four subclasses of LDL and five subclasses of HDL (col. 1, ll. 48 to 52). Otvos discloses that various subclasses of lipoproteins may provide more reliable markers of the metabolic conditions that predispose individuals to a greater or lesser risk of heart disease (col. 1, ll. 59 to 62). Otvos discloses that using LDL subclass information may reveal a patient that does not have lipid profile indicating high risk when the total LDL is considered, but is still in need of treatment (col. 16, ll. 53 to 57). In Figure 11, Otvos depicts that an examination of the total HDL concentration of 32 mg/dl results in a positive risk factor when the large HDL subclass which is 11 nmo/L is examined, it too results in a

1 positive risk factor. As such, Otvos does not disclose that an advantage can
2 be achieved by examining the large HDL subclass.

3 Krauss does not disclose a diagnostic engine for analyzing patient test
4 results for subclasses of LDL particles, subclasses of HDL particles, and
5 identifying patients who do not have hyperlipidemia based on total LDL
6 cholesterol and total HDL cholesterol, but are in need of treatment wherein
7 the particle subclasses include HDL 2b.

8
9 PRINCIPLES OF LAW

10 The test for obviousness is what the combined teachings of the
11 references would have suggested to one of ordinary skill in the art. *See In re*
12 *Kahn*, 441 F.3d 977, 987-88 (Fed. Cir. 2006); *In re Young*, 927 F.2d 588,
13 591 (Fed. Cir. 1991) and *In re Keller*, 642 F.2d 413, 425 (CCPA 1981).

14 Rejections on obviousness grounds cannot be sustained by mere
15 conclusory statements; instead, there must be some articulated reasoning
16 with some rational underpinning to support the legal conclusion of
17 obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). A finding of
18 obviousness can be based on the effects of demands known to the design
19 community or present in the marketplace; or the background knowledge
20 possessed by a person having ordinary skill in the art, as support for his
21 conclusion that there existed at the time of the invention an apparent reason
22 to modify the sleeve nut and grommet of Borst in the manner claimed. *See*
23 *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, ___, 127 S. Ct. 1727, 1740-41
24 (2007).

ANALYSIS

Rejection of claims 22, 24 to 28 and 38

We will not sustain the Examiner's Rejection. Although we agree with the Examiner that Otvos discloses that more risk factors can be determined when subclasses of LDL are examined, Otvos does not disclose that examination of HDL subclasses leads to the same advantage. In fact, a review of Figure 11 of Otvos indicates that the total HDL concentration lead to one risk factor and the large HDL also lead to one risk factor and as such does not disclose that an advantage is obtained by examining HDL subclasses. And while the Appellants' Specification discloses that subclasses of LDL or HDL may be considered risk factors, the Specification does not disclose which subclass concentrations are considered risk factors. Further, none of the references discloses that the subclasses analyzed must include HDL 2b or any reason to include HDL 2b. Therefore, there is no reason to include subclass HDL 2b in Levin as modified by Otvos system.

In view of the foregoing, we will not sustain the Examiner's rejection of claim 38 and claims 22 and 24 to 28 dependent thereon.

We will also not sustain the Examiner's rejection of claim 23 as being unpatentable over Levin, Otvos, AAPA, Krauss and Surwit because claim 23 depends from claim 38, and Surwit does not cure the deficiencies noted above for the Levin, Otvos, Krauss, AAPA combination.

CONCLUSION OF LAW

On the record before us, Appellants have shown that the Examiner erred in rejecting the appealed claims.

DECISION

The Examiner's rejection of claims is reversed.

REVERSED

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